REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1-71, 113 and 114 are currently pending with entry of this amendment. Claims 1 to 58, 113 and 114 are currently under consideration, and claims 59 to 71 have been withdrawn from consideration due to a restriction requirement. Claims 1, 7, 8, 12, 13 and 57 are currently amended. Claims 113 and 114 are new. Claims 72-112 have previously been cancelled.

The current amendments introduce no new matter and support for the amendments is replete throughout the specification and claims as originally filed. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter, or agreement with any objection or rejection of record.

With regard to amended claim 1, support for transport mechanisms having one or more sample processing components insertable into each of two or more sample receiving regions at substantially the same time can be found throughout the specification. For example, see the Figures and paragraph 16. Support for sample processing components configurations can be found, e.g., in the Sample Processing Components section starting at paragraph 97.

With regard to claims 7 and 8, the amendments are merely to provide a more appropriate claim dependency and do not affect the scope of the claims.

With regard to claims 12 and 13, support for the claimed arrangements and configurations of clustered sample receiving regions can be found throughout the specification. For example, the "Rotors" section starting at paragraph 95, the figures, and paragraphs 78, 82, 90, 92, 116 and 172.

With regard to claim 57, the amendment adjusts numerical representation of system components to reflect changes in amended claim 1, upon which claim 57 is dependent. The amendments also adjust certain terms to clarify antecedence within the claim.

With regard to claim 113, support for systems having both a sample processing component transport mechanism and a robot capable of inserting sample vessels can be found throughout the specification. For example, see paragraphs 21, 23, and 28. This new claim does not include any elements not previously presented and should not require an additional search for examination.

With regard to claim 114, support for systems having substantially non-vertical sample receiving regions can be found throughout the specification. For example, see the Figures and paragraphs 35 and 78. This new claim does not include any elements not previously presented and requires no new search for examination.

35 U.S.C. §112, Second Paragraph.

Claims 7, 8, and 57 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite based on issues of antecedence associated with certain claim terms.

Claim 7 was rejected for reciting a "second" motor when the claims upon which it was dependent do not recite a "first" motor. Claim 8 was rejected for referring to "the first" motor when the claims upon which it was dependent do not recite a "first" motor. These issues have been resolved by amendments making the claims each dependent on claim 6, which recites a first motor.

Claim 57 was rejected for reciting "the" fraction collector when "a" fraction collector was not previously recited in claim 1, upon which it is dependent. This antecedence issue has been resolved by amending claim 57 to recite "a" fraction collector.

Claim 57 was also rejected for reciting "the sample receiving elements" allegedly without proper antecedent basis. To provide proper antecedence in this case, the term has been amended to read "the sample receiving regions".

Because antecedence has been corrected, Applicants respectfully request the rejections based on 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. §102.

Claims 1-9, 14, 16, 19-21, 29-38, 42-44, 46, 48, 49, 53, 54, 57 and 58 were rejected under 35 U.S.C. §102 as allegedly anticipated by Yoshida (U.S. 4,708,940). Applicants traverse.

In order for a reference to anticipate an invention, "all limitations of the claim are found in the reference, or 'fully met' by it." Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983). With respect to all the claims rejected for alleged anticipation, this requirement is not met.

Amended Claim 1, as currently amended, is directed to an automated centrifuge that comprises, in addition to a rotor, either or both of the following elements: 1) a transport mechanism configured to move one or more sample processing components proximal to or within each of two or more sample receiving regions at substantially the same time; and, 2) a robot capable of inserting at least two sample vessels into the sample receiving regions at substantially the same time, wherein the sample receiving regions comprise one or more non-vertical clusters.

The Action does not allege that Yoshida describes the alternate clause 2) robot. This is because Yoshida does not include a robot that can insert sample vessels into sample receiving regions. Yoshida makes it clear, e.g., at column 4, line 38 that an operator inserts "pots" into "holders" manually, one at a time. Therefore, Yoshida does not anticipate the robotic alternative at clause (2) of claim 1.

The Action does allege that Yoshida discloses a transport mechanism configured to move sample processing components within sample receiving regions of a rotor. The Action asserts that the sample pipe 12 and liquid level sensing electrode 17 on an arm 35 (see Figure 6) constitute two sample processing components. However, Yoshida does not describe an automated centrifuge that has a transport mechanism configured to move one or more sample processing components proximal to or within each of two or more sample receiving agents at the same time. Therefore, Yoshida does not anticipate claim 1 as currently amended.

New independent claim 113 requires both of the alternative clauses of claim 1—both a transport mechanism configured to move sample processing components proximal to or within two or more sample receiving agents at the same time, and a robot capable of inserting at least two sample vessels into the sample receiving regions at substantially the

same time. Yoshida does not describe any centrifuge that includes either of these two components. Therefore, Yoshida can not anticipate claim 113.

New independent claim 114 requires that the automated centrifuge rotor have substantially non-vertical sample receiving regions. Yoshida teaches "pot holders are attached to the rotor 2 so they take a vertical attitude", see column 3, line 32. The centrifuges disclosed in Yoshida are only of the swinging bucket (vertical receiving) type. Therefore, Yoshida does not describe the substantially non-vertical sample receiving regions of claim 114. Because Yoshida does not describe all limitations of claim 114, it does not anticipate the claim.

The remaining rejected claims depend from claim 1. Since claim 1 is not anticipated by Yoshida, as discussed above, the dependent claims likewise cannot be anticipated by this reference. Moreover, the rejected dependent claims recite additional claim limitations that also are not described by Yoshida. These include, for example:

1) The second motor of claim 7.

2) The claim 29 robot capable of inserting sample vessels.

3) The claim 31 controller directing insertion of multiple sample processing components to multiple receiving regions.

4) The claim 32 clusters of sample receiving elements, groups of sample processing components, or insertion of the groups into the clusters.

5) The claim 36 controller direction of insertion or removal of sample processing component groups with respect to clusters.

6) The claim 37 direction of sample processing component groups into adjacent clusters.

7) The claim 43 tracking of processing operations for samples or vessels.

8) The claim 44 vessel feature mating with a robot.

9) The claim 46 rinse container.

10) The claim 49, claim 53 and claim 57 specimen collectors, as described in Applicants' specification.

11) The claim 54 refrigerated rotor or specimen collector.

Because Yoshida does not describe an automated centrifuge having each element set forth in Applicants' claims, the rejections for alleged anticipation should be withdrawn.

35 U.S.C. §103(a).

Claims 10-13, 15, 17, 18, 22-28, 39-41, 45, 47, 50-52 and 56 are variously rejected for alleged obviousness based on Shimada in view of Pang (U.S. 6,060,022), Alam (U.S. 5,792, 050), Roginski (U.S. 4,927,545), Taylor (U.S. 4,822,331), and/or Feldman (U.S. 5,445,958). Applicant traverses.

Three requirements must be met for a *prima facie* case of obviousness. First, the prior art reference must teach all of the limitations of the claims. M.P.E.P § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. The teaching or suggestion to combine and the expectation of success must be both found in the prior art and not based on Applicants' disclosure. M.P.E.P. § 2143.

The claims are not obvious based on Yoshida in light of Pang. Claims 10-13, 15, 17, 18 and 23 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida in view of Pang. The rejected claims ultimately depend from claim 1 which, as amended herein, is not anticipated by Yoshida because Yoshida does not describe an automated centrifuge having each element set forth in Applicants' claims.

First, Yoshida does not describe an automated centrifuge having a transport mechanism configured to move one or more sample processing components proximal to or within each of two or more sample receiving regions at substantially the same time. Pang does not describe this claim element that is not described in Yoshida. In particular, Pang does not teach sample processing while the samples are in a centrifuge rotor. In contrast, Pang states that, after centrifuging, "[t]he individual containers [12] are then unloaded from the buckets [1200] for further processing." Therefore, the combination of Yoshida and Pang does

teach all elements of this alternative embodiment of claim 1, so claim 1 and all claims that depend from claim 1 are not *prima facie* obvious over these references.

With respect to the second alternative embodiment of the automated centrifuge of claim 1, Yoshida does not describe a centrifuge having a robot capable of inserting at least two sample vessels into the sample receiving regions at substantially the same time, wherein the sample receiving regions comprise one or more non-vertical clusters. Pang does not provide this element that is lacking in Yoshida. Therefore this second embodiment of the automated centrifuge is not *prima facie* obvious over the combination of Yoshida and Pang.

Each of rejected claims 10-13, 15, 17, 18 and 23 depend from claim 1. Because the cited references do not teach all elements of independent claim 1, the dependent claims are likewise not *prima facie* obvious over these references.

With regard to claims 15, 17, and 23, these claims are directed to automated centrifuges that include additional elements that re not described by either of the cited references. Claim 15 is directed to an automated centrifuge having a transport mechanism configured to substantially simultaneously insert a group of sample processing components into a cluster. Neither cited reference simultaneously insert anything into a cluster. Claim 17 is directed to an automated centrifuge that has group of sample processing components configured to perform sample processing operations on numerous samples at the same time. Neither cited reference processes more than one sample at a time. Claim 23 is directed to an automated centrifuge in which sample processing components are arranged in pairs of components so that the pair of components can be moved into a pair of sample receiving elements. Neither cited reference describes a centrifuge that includes a transport mechanism that moves a pair of components into a pair of sample receiving elements. Therefore, for these additional reasons, the rejections of these claims should be withdrawn.

Furthermore, no motivation for combining Yoshida and Pang can be found. Nothing in the cited art suggests the combination. The Action does not allege that a motivation exists in the art generally to make such a combination, nor is any such motivation apparent. Moreover, no motivation can be found because the systems are different devices

solving different problems. Yoshida relates to a serial processing of samples for input to a clinical analyzer, yielding quick results for an individual sample; while Pang relates to a sample processing system that sorts large numbers of samples for batch processing and parallel analysis. One can not simply mix and match components, as apparently suggested by the Action. Because no motivation is cited for the combination, the rejections further fail the three part test for presentation of a *prima facie* case outlined above.

Because the cited references do not provide all limitations of the claims, and because no motivation to combine the cited references is found in the cited art, Applicants respectfully request that rejections for alleged obviousness based on Yoshida and Pang be withdrawn.

The claims are not obvious based on Yoshida in light of Alam. Claim 22 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Yoshida in view of Alam.

As noted above, Yoshida fails to provide the limitations of claim 1, upon which claim 22 depends. Alam also fails to provide these limitations. Alam simply describes sonication of blood cells to form a lysate. Alam does not describe a robot for inserting samples into a centrifuge or a transport mechanism for moving sample processing components into or near sample receiving regions. Moreover, neither Alam nor Yoshida describes automated centrifuges having the limitations set forth in claim 14, from which claim 22 also depends, such as, for example, a group of sample processing components. Because the cited combination of references does not provide the limitations set forth in the claims upon which claim 22 depends, the combination of references do not render claim 22 *prima facie* obvious.

In the rejection, an attempt is made to provide the claim 22 limitations missing from the references by citing *In re Harza*, 124 USPQ 378, (CCPA 1960). The holding in *In re Harza* was that mere duplication of parts that are old in the art does not have patentable significance. However, here the group of sample processing components does not merely include duplicates of an old component. Claim 22 is directed to novel combinations of sonication rods and transport tubes that do not exist in the prior art. Because the groups of

claim 22 have a plurality of novel sample processing component combinations, *In re Harza* is not on point. Moreover, the rejection appears to be applying a *per se* rule that duplication of parts has no patentable significance. The Federal Circuit addressed the impropriety of *per se* rules in *In re Ochiai*, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995), stating:

> The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention - including all its limitations - with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease.

Moreover, one of ordinary skill in the art would have had no motivation for combining the teachings of Yoshida with those of Alam. Nothing in the cited art suggests the combination. The Action does not allege that a motivation to combine the references exists in the art generally, nor is any reason motivating the combination apparent. Moreover, no motivation can be found because the systems of Yoshida and Alam are different devices solving totally different problems; here again, one can not simply mix and match components, as suggested by the Action. For example, Yoshida describes a sequential mechanical system of pumps and tubes for analysis of blood; whereas Alam describes a non-invasive electronic device that reads pH through the skin of a patient. Because no motivation is cited for the combination, the rejections further fail the three part test for presentation of a *prima facie* case.

Because the cited references do not provide all limitations of the claims, and because no motivation exists for combining the references, *prima facie* obviousness is not established. Applicants therefore request that rejections for alleged obviousness based on Yoshida and Alam be withdrawn.

The claims are not obvious based on Yoshida in light of Roginski. Claims 24, 25 and 41 are rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida in view of Roginski.

Each of the rejected claims is dependent on claim 1, which is not anticipated by Yoshida for reasons discussed above. Roginski does not provide a teaching of the claim elements that are not described by Yoshida. In particular, Roginski does not describe a robot capable of inserting at least two sample vessels into sample receiving regions of a rotor at the same time, or a transport mechanism that can move sample processing components into or near two or more sample receiving regions at substantially the same time. Because claim 1 is not obvious over the cited combination of references, these dependent claims are likewise not *prima facie* obvious over these references.

With regard to claim 25, in particular, Roginski does not disclose, and the Examiner has failed to allege, a robot that grasps the inside surface of a sample vessel. Therefore, a *prima facie* case has not been made, and the rejection must be withdrawn.

Moreover, one of ordinary skill in the art would have had no motivation for combining the teachings of Yoshida with those of Roginski. Nothing in the cited art suggests the combination. The Action does not allege that a motivation to combine these references exists in the art generally, nor is any rationale supporting such a motivation to combine apparent. Moreover, no motivation can be found because the analysis system of Yoshida and sample handling systems of Roginski are different devices solving different problems; one can not simply mix and match components, as suggested by the Action. Because no motivation is cited for the combination, the rejections further fail the three part test for presentation of a *prima facie* case.

Because the cited references do not provide all limitations of the claims, and there is no motivation to combine the references, these claims are not *prima facie* obvious over the cited references. Consequently, Applicants request that rejections for alleged obviousness based on Yoshida and Roginski be withdrawn.

The claims are not obvious based on Yoshida in light of Pang and Roginski. Claims 26-28 and 45 are rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida in view of Pang and Roginski.

As discussed above, neither Pang nor Roginski provide the limitations of claim 1 that are not found in Yoshida. For example, Yoshida, Pang and Roginski all fail to describe a robot capable of inserting at least two sample vessels into sample receiving regions at the same time and a transport mechanism that is configured to move one or more sample processing components proximal to or within each of two or more sample receiving regions at substantially the same time. Because the rejected claims are dependent on non-obvious claim 1, they too are not obvious over the cited references.

The Examiner again cited *In re Harza* in an effort to provide some of the limitations not found in the cited references. As the Examiner has stated, according to *In re Harza*, the mere duplication of parts, without any new or unexpected results, is within the ambit of one skilled in the art. However, as noted above, it is improper to treat *In re Harza* as creating a *per se* rule of unpatentability. Moreover, Applicants note that the interacting grouped components of the present invention are not merely a duplication of individual parts. Interactions of the grouped parts in the systems of the invention require unobvious group and mounting configurations to overcome problems unique in the group interaction compared to the simple single part interactions of Yoshida. For example, insertion of grouped processing components or vessels into clustered receiving regions presents the additional problems of group member spacing. Insertion of group members into multiple receiving regions uses radial orientation of the group to align the members with the receiving region openings in a coordinated fashion. Insertion of group members uses axial alignment and insertion motions of each member with its corresponding receiving region, e.g., without interfering with the alignment and insertion other group members. The groups and clusters of the claims have a new character different from the individual unassociated parts and are not mere duplications of independent individual parts, as was the case in *In re Harza*. Therefore, the claims meet the standard articulated in *In re Harza*.

Since these claims are not *prima facie* obvious over the cited references, Applicants respectfully request that this rejection be withdrawn.

The claims are not obvious based on Yoshida in light of Taylor. Claims 39 and 40 are rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida in view of Taylor.

Claims 39 and 40 are dependent on claims 30 and 1. As noted above, Yoshida fails to describe each element of claim 1. Taylor fails to provide these limitations. Taylor does not describe robots that are capable of introducing at least two sample containers into sample receiving regions of a centrifuge rotor. Nor does Taylor describe a transport mechanism that is configured to move one or more sample processing components proximal to or within each of two or more sample receiving regions at substantially the same time. Because the combination of references does not provide all limitations of a claim upon which claims 39 and 40 depend, the combination can not render them obvious.

Because the cited references do not provide all limitations of the claims, the rejections for alleged obviousness based on Yoshida and Taylor should be withdrawn.

Claims are not obvious in view of Yoshida alone. Claims 47 and 56 were rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida.

Claims 47 and 56 are dependent on claim 1. Because Yoshida alone fails to describe all limitations of claim 1, as discussed above, it can not render these dependent claims obvious.

With regard to claim 47 in particular, the Examiner admits that Yoshida does not disclose any of the claim limitations, such as, e.g., a tube bin, a rod bin and a runoff ramp. In addition, the rejected claim 47 is also dependent on claim 46 systems comprising a rinse container with many limitations not found in the cited art. However, no rationale or comments of any kind were presented in the Office Action outlining a case for rejection of claim 46. Moreover, with respect to claim 47, the Examiner is applying the holding of *In re Harza* as a *per se rule* of unpatentability without making the required fact-specific analysis of the claims and the cited references that is required. Because a *prima facie* case has not been made, Applicants request withdrawal of the rejections.

With regard to claim 56, in the conclusory rejection at the end of Office Action section 6, the Examiner is apparently basing the rejection on Yoshida in light on the skill of one in the art. The rationale to modify prior art does not have to be expressly stated in the prior art, but may be reasoned from knowledge generally available to one of ordinary skill in the art. However, Applicant notes that the Examiner must present convincing line of reasoning supporting such a rejection. See M.P.E.P. § 2144 and *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). Here, no reasoning was presented. Because a *prima facie* case according to M.P.E.P. § 2143-4 has not been made, the rejection should be withdrawn.

The claims are not obvious based on Yoshida in light of Feldman. Claims 50-52 are rejected under 35 U.S.C. §103(a) as allegedly obvious based on Yoshida in view of Feldman.

Claims 50 to 52 are dependent on claim 1, which is novel and unobvious, as described above. Therefore, claims 50 to 52 are not obvious. As noted above, Yoshida fails to provide the limitations of claim 1. Feldman is a process for purifying blood factors and merely describes the use of a nickel-chelate column. Thus, Feldman does not provide any limitations concerning a robot or a transport mechanism not provided by Yoshida with regard to claim 1.

The Examiner has not provided a rationale or any statement of facts in support for rejection of claim 48, from which the present rejected claims are dependent. Because claim 48 contains many limitations not found in the cited references, and has not been rejected for alleged obviousness, neither it nor its dependent claims 50 to 52 can be considered obvious.

With regard to claim 50, the combination of Yoshida and Feldman does not provide a description of "sample processing components fluidly coupled to a sample purification component." With regard to claim 51, the combination of Yoshida and Feldman does not provide a description of "sample processing components fluidly coupled to a resin bed." With regard to claim 52, the combination of Yoshida and Feldman does not provide a description of "a plurality of purification columns." The Action does not identify where

these limitations may be found in the references, and thus has failed to make a *prima facie* case.

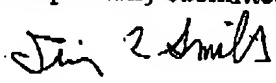
Because the cited references do not provide all limitations of the claims, Applicants respectfully request the rejections for alleged obviousness based on Yoshida and Feldman be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1547.

Respectfully submitted,



Timothy L. Smith, Ph.D.
Reg. No. 35,367

GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION
10675 John Jay Hopkins Drive, Suite E225
San Diego, CA 92121
Tel: (858) 812-1547
Fax: (858) 812-1981

Attachments:

1) A transmittal sheet;
2) A fee transmittal sheet;
3) A petition to extend the period of response for 3 months; and,
4) A receipt indication postcard.